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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,515

03/22/2004

Tom F. Lue

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EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

05/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,515	Applicant(s) LUE ET AL.	
	Examiner CELINE X. QIAN	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,9,11-15,21 and 23-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4,5,9,11-13,21,23-28,37 and 38 is/are allowed.
- 6) ☒ Claim(s) 14,15,29-36 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/15/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 4, 5, 9, 11-15, 21, 23-39 are pending in the application.

This Office Action is in response to the Amendment filed on 2/11/08.

Response to Amendment

Acknowledgment is made of the amendment to the specification (change of the title).

The amendment is entered.

The information disclosure statement (IDS) submitted on 5/15/07 has been considered by the examiner.

The rejection of claims 1, 4, 5, 9, 11-15, 21-28 under 35 U.S.C.112 1st paragraph has been withdrawn in light of the amendment.

Claim 14, 15, 29-36 and 39 are rejected under 112 1st paragraph for reason stated below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 15, 29-36 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 14 and 29 recites the new limitation of “the male erectile dysfunction is preventable or treatable by increasing neovascularization and the administration of bFGF causes

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neovascularization thereby preventing or treating the male erectile dysfunction." Applicants assert that this amendment is supported by paragraph 17 and 134 of the specification. However, the teaching in paragraph 17 is directed to the background of treating vasculopathies with VEGF, which increased neovascularity in animal models and improved symptomatic angina and would healing in humans with inoperable heart disease and critical limb ischemia. The teaching in paragraph 134 is directed to a specific working example, wherein the animals having venous leak treated with VEGF protein demonstrate improved erectile function. Applicants hypothesize that increased cavernosal neovascularity may lead to functional or structural changes in the nerve and smooth muscles, or the direct effect of VEGF on the nerve and smooth muscle may also play a role since VEGF has been reported to have a direct trophic effect on the penile smooth muscle cells and spinal neurons in culture (see last four lines of paragraph 134). It appears that the teaching from the specification of these two paragraphs is directed to hypothesized mechanism of action of VEGF on vasculopathies, and its protective action on ED in animal model. However, there is no evidence from the specification that VEGF causes neovascularization resulting in prevention or treatment of the male erectile dysfunction in the mammal. Moreover, there is no teaching from the specification that bFGF causes neovascularization resulting in prevention or treatment of the male erectile dysfunction in the mammal. Therefore, the teaching from the specification, paragraph 17 and 134, does not support the newly added limitation in the context of a method for treating or preventing male erectile dysfunction that is preventable or treatable by increasing neovascularization, comprises administering to a male mammal an effective amount of bFGF, and wherein bFGF causes neovascularization resulting in prevention

or treatment of the male erectile dysfunction in the mammal. As such, the amendment introduces new matter. Claims 15, 30-36 are included because they depend on claims 14 and 29.

Claim 39 recites the bFGF is administered via a microsphere. Applicants assert that this limitation is supported by paragraph 80 and 86. However, although paragraph 80 and 86 describes a number of pharmaceutical acceptable carrier, it does not include a microsphere. Therefore, this limitation constitutes new matter.

Conclusion

Claims 1, 4, 5, 9, 11-13, 21, 23-28, 37 and 38 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian Ph.D./
Primary Examiner, Art Unit 1636